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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,560	02/01/2007	Serdar Sel	23593	2078

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
06/13/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/574,560	SEL ET AL.
	Examiner	Art Unit
	AMY BOWMAN	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/14/11*.	6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 recites that the catalytic domain has the sequence of SEQ ID NO: 154 “or a modified sequence with comparable biological effect”. However, the specification does not describe the genus of sequences that are modified in any possible manner that in fact have comparable biological effect to SEQ ID NO: 154.

Therefore, one of ordinary skill would not be able to recognize that applicant was in possession of the claimed genus at the time of filing given that one of skill wouldn’t be able to envision the genus of claimed molecules.

Furthermore, the claim requires for the binding arms to be “respectively complementary“ to two regions of GATA 3 mRNA so that they hybridize with the mRNA. The specification does not describe any specific structural criteria to allow the skilled

artisan to envision which sequences meet the limitation of being respectively complementary and which would not in order for the skilled artisan to be able to recognize that applicant was in possession of the claimed genus at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun et al. (WO 00/09672).

Sun et al. teach a DNAzyme with a catalytic core identical to instant SEQ ID NO: 154, wherein the catalytic core is attached to a righ and left substrate binding domain. See the SCORE file titled "20110525_152905_us-10-574-560b-154.rng", result #1 as follows:

RESULT 1
AAZ57033
ID AAZ57033 standard; DNA; 15 BP.
XX
AC AAZ57033;
XX
DT 19-MAY-2000 (first entry)
XX
DE Catalytic domain of DNAzyme cleaving human c-myc RNA.
XX
KW DNAzyme; c-myc RNA; restenosis; angioplasty; catalytic domain;
KW gene therapy; vasotropic; ss.

XX
OS Homo sapiens.
XX
PN WO200009672-A1.
XX
PD 24-FEB-2000.
XX
PF 12-AUG-1999; 99WO-IB001484.
XX
PR 13-AUG-1998; 98US-0096374P.
XX
PA (JOHJ) JOHNSON & JOHNSON RES PTY LTD.
XX
PI Sun L, Cairns MJ;
XX
DR WPI; 2000-224325/19.
XX
PT New DNAzyme that cleaves c-myc RNA, useful for preventing restenosis
PT after angioplasty, comprises catalytic domain and flanking binding
PT domains.
XX
PS Claim 1; Page 27; 44pp; English.
XX
CC The invention provides a DNAzyme that cleaves specifically c-myc RNA and
CC comprises (contiguously in the 5' to 3' direction) a binding domain, a
CC catalytic domain and a second binding domain. The DNAzyme, optionally
CC when coated on an angioplasty stent, is used to inhibit onset of
CC restenosis, specifically after angioplasty. The DNAzyme is an effective
CC treatment for inhibition of restenosis and it lacks the side effects of
CC prior art treatments such as intra-coronary radiation. The present
CC sequence represents the catalytic domain of the DNAzyme of the invention
XX
SQ Sequence 15 BP; 5 A; 4 C; 4 G; 2 T; 0 U; 0 Other;

Query Match 100.0%; Score 15; DB 1; Length 15;
Best Local Similarity 100.0%;
Matches 15; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 GGCTAGCTACAACGA 15
Db 1 GGCTAGCTACAACGA 15

Although Sun et al. does not teach the DNAzyme as targeted to GATA-3, the DNAzyme of Sun et al. meets each of the instant structural limitations because it has a right and left substrate arm that would be complementary at some level to GAT3 mRNA, given that any A would bind to any T and any G would bind to any C, etc.

The instant claims do not require any specific level of complementarity between the arms and the target sequence.

Sun et al. teach a composition comprising the DNAzyme and a pharmaceutically acceptable carrier.

Since Sun et al. teach a DNAzyme meeting the instant structural limiations, the DNAzyme of Sun et al. would necessarily meet the instantly recited outcomes such as GATA-3 inactivation and cleavage at specific types of binding sites, absent evidence to the contrary. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property.

Therefore, the instant invention is anticipated by Sun et al.

Claims 2, 4, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Blatt et al. (WO 02/068637 A2).

Blatt et al. teach a DNAzyme with a catalytic core identical to instant SEQ ID NO: 154, wherein the catalytic core is attached to a right and left substrate binding domain. See the SCORE file titled "20110525_152833_us-10-574-560b-40.rng", result #2 as follows:

RESULT 2

ACN32537

ID ACN32537 standard; RNA; 31 BP.

XX

AC ACN32537;

XX

DT 22-APR-2004 (first entry)

XX

DE WNV minus strand DNAzyme SEQ ID NO 32553.

XX

KW WNV; West Nile Virus; antiinflammatory; cytostatic; hepatotropic;

KW virucide; neuroprotective; antibacterial; replication; pancreatitis;

KW encephalitis; myocarditis; meningitis; infection; hepatitis;

KW liver failure; cancer; cirrhosis; Hammerhead; Inozyme; DNAzyme;

KW Amberzyme; Zinzyme; ss.

XX

OS West Nile Virus.

XX

PN WO200268637-A2.

XX

PD 06-SEP-2002.

XX

PF 19-OCT-2001; 2001WO-US048350.

XX

PR 20-OCT-2000; 2000US-0242411P.

XX

PA (RIBO-) RIBOZYME PHARM INC.

PA (BLAT/) BLATT L.

PA (MCSW/) MCSWIGGEN J A.

XX

PI Blatt L, Mcswiggen JA;

XX

DR WPI; 2002-706994/76.

XX

PT New nucleic acid molecule that modulates replication of West Nile Virus

PT (WNV), useful for treating a condition related to WNV infection e.g.

PT pancreatitis, meningitis, hepatocellular carcinoma or cirrhosis.

XX

PS Claim 24; SEQ ID NO 32553; 495pp; English.

XX

CC The invention relates to nucleic acid molecules that modulate replication

CC of the West Nile Virus (WNV). The nucleic acid molecules are useful for

CC treating a condition related to WNV infection e.g. pancreatitis,

CC encephalitis, myocarditis, meningitis, neurologic infection, hepatitis,

CC liver failure, hepatocellular carcinoma or cirrhosis. The nucleic acid

CC molecule is selected from the group of ribozymes consisting of

CC Hammerhead, Inozyme, G-cleaver, DNAzyme, Amberzyme and Zinzyme. The

CC nucleic acid molecules further comprise at least five ribose residues, at

CC least ten 2'-O-methyl modifications, phosphorothioate linkages on at

CC least three of the 5' terminal nucleotides and a 3' end modification of a

CC 3'-3' inverted abasic moiety. Nucleic acid molecules SEQ ID NO 1 to 37080

CC are claimed; however, SEQ ID NO 2194-2206 and 17502-17514 are not given

CC in the specification. The present sequence is that of a nucleic acid

CC molecule of the invention

XX

SQ Sequence 31 BP; 8 A; 8 C; 11 G; 4 T; 0 U; 0 Other;

Query Match 76.4%; Score 25.2; DB 1; Length 31;

Best Local Similarity 90.0%;

Matches 27; Conservative 0; Mismatches 3; Indels 0; Gaps 0;

Qy 3 GGATGGAGGCTAGCTACAACGAGTCTTGGA 32

Db 2 GGAGGCAGGCTAGCTACAACGAGTCCTGGA 31

Although Blatt et al. does not teach the DNAzyme as targeted to GATA-3, the DNAzyme of Blatt et al. meets each of the instant structural limitations because it has a right and left substrate arm that would be complementary at some level to GAT3 mRNA, given that any A would bind to any T and any G would bind to any C, etc.

Furthermore, the sequence of Blatt et al. only differs from instantly claimed SEQ ID NO: 40 (specific DNAzyme of claim 3) at 5 positions and therefore would certainly be expected to hybridize to GATA 3 mRNA.

The instant claims do not require any specific level of complementarity between the arms and the target sequence.

Blatt et al. teach a composition comprising the DNAzyme and a pharmaceutically acceptable carrier.

Since Blatt et al. teach a DNAzyme meeting the instant structural limiations, the DNAzyme of Blatt et al. would necessarily meet the instantly recited outcomes such as GATA-3 inactivation and cleavage at specific types of binding sites, absent evidence to the contrary. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property.

Therefore, the instant invention is anticipated by Blatt et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imagawa et al. (Blood, 1997, pages 1430-1439), in view of Sun et al. (Pharmacological Reviews, 2000, 325-347).

The references are of record and cited on the IDS filed on 1/14/11.

Imagawa et al. teaches inhibition of GATA 3 with an antisense oligonucleotide. Imagawa et al. is evidence that it was known to specifically inhibit GATA 3 with an antisense nucleic acid in combination with a pharmaceutically acceptable carrier.

Sun et al. teach the design of DNAzymes and specifically teach the catalytic core identical to instant SEQ ID NO: 154. Sun et al. teach that DNAzymes have a much greater half-life in vivo than ribozymes. Sun et al. teach that the stability can even greater be supplemented by incorporation of modifications (see page 330, for example). Sun et al. teaches incorporation of 3'-3' inversion, inverse thymidine on the 3' end, or FAM label on the 5' end.

Sun et al. teach that DNAzymes with this catalytic core (10-23 DNA enzyme) has the ability to cleave almost any RNA sequence with high specificity provided it contains a purin-pyrimidine dinucleotide.

It would have been obvious to design a DNAzyme targeting GATA-3 wherein the DNAzyme has the cataltyic core of SEQ ID NO: 154 and hybridizing arms that are complementary to GATA 3 mRNA. It would have been obvious to incorporate the instant modifications.

One would have been motivated to design a DNAzyme targeting GATA-3 wherein the DNAzyme has the cataltyic core of SEQ ID NO: 154 and hybridizing arms that are complementary to GATA 3 mRNA because it was known to inhibit GATA 3 with antisense nucleic acids, as evidenced by Imagawa et al. and DNAzymes with the same catalytic core were known to be stable inhibitory molecules that can target virtually any

mRNA. Therefore, one would have been motivated to utlize a DNAzyme rather than an antisense nucleic acid as a matter of design choice.

One would have been motivated to incorporate the instant modifications because Sun et al. teach that such modificaitons enhance stability of the enzymatic molecule.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

It is noted that the sequence of claim 3 is free of the prior art. However, it is rejected under 35 USC 112, 1st paragraph above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 6:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita can be reached on (571) 272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMY BOWMAN
Primary Examiner
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